Company Announcement
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Zealand Pharma's partner Sanofi has announced a New Drug Application for lixisenatide in the US accepted for review by FDA

Copenhagen, 19 February 2013 - Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) announces that its partner Sanofi (EURONEXT:SAN and NYSE:SNY) has today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for lixisenatide as the first once-daily prandial GLP-1 receptor agonist for the treatment of adults with Type 2 diabetes. Sanofi submitted the NDA for lixisenatide in the US in December 2012, and FDA acceptance of the filing follows the announcement on 4 February 2013 of European Commission approval of lixisenatide (Lyxumia® [1]) in the European Union (Company Announcement no. 2/2013).

The NDA for lixisenatide is based on results from the GetGoal clinical Phase III program, which showed that treatment with lixisenatide gave significant reductions in HbA1c, a pronounced post-prandial glucose (PPG)-lowering effect and a beneficial effect on body weight in adult patients with Type 2 diabetes. GetGoal results also showed that lixisenatide had a favorable safety and tolerability profile in most patients, with mild and transient nausea and vomiting, the most common adverse events observed in the GLP-1 receptor agonist class, and a limited risk of hypoglycemia.

The international GetGoal program included 11 clinical trials involving more than 5,000 patients with Type 2 diabetes[2], with a large number of patients studied to evaluate a GLP-1 receptor agonist in combination with basal insulin (1,250 patients treated with lixisenatide and placebo in three trials). The addition of lixisenatide to basal insulin was studied because these medicines target separate components of HbA1c, an important measure of longer term blood glucose control. Lixisenatide has a pronounced PPG-lowering effect, which complements the predominantly fasting plasma glucose (FPG)-lowering effect of basal insulin. For patients treated with basal insulin who have controlled FPG but who, due to the progression of Type 2 diabetes, are no longer able to achieve their HbA1c goal, adding lixisenatide could be an effective treatment strategy to achieve better glucose control.

Commenting on the news, **David Solomon, President and CEO of Zealand Pharma, said:** *"The FDA's acceptance for review of the NDA filing for lixisenatide, Zealand's first drug invention, in the U.S. is yet another important step forward in our goal to help provide new peptide medicines for better treatment of Type 2 diabetes patients globally."* **He added**: *"This positive news follows the European approval of lixisenatide, branded as Lyxymia®, earlier this month which was a strong validation of the product's therapeutic relevance."*

"We are very pleased to announce the FDA acceptance of our submission for lixisenatide in the U.S.," said **Pierre Chancel, Senior Vice President, Global Diabetes at Sanofi**. *"This important milestone is the result of our company's continuing worldwide effort to meet the needs of people living with diabetes, and we look forward to working with the FDA during the review process."*

Financial guidance for 2013 and the terms of the Sanofi agreement
Under the license agreement with Sanofi, which covers lixisenatide and combination products, including lixisenatide, Zealand Pharma is entitled to tiered low double-digit percentage royalties on global net sales of lixisenatide (Lyxumia®) and fixed low double-digit percentage royalties on full net sales of combination products, including lixisenatide[3].

Further, the company is eligible to receive remaining development, regulatory and sales milestone payments of up to USD 215 million, which include USD 40 million for a depot formulation of lixisenatide not currently in active development[3].

There is no milestone payment to Zealand Pharma related to FDA's acceptance of the NDA for lixisenatide. Zealand Pharma will provide financial guidance for 2013 in connection with the release of its 2012 full-year announcement on 14 March 2013.

References

1. Lyxumia® is the proprietary name approved by the European Medicines Agency (EMA) for lixisenatide in Europe.
2. http://clinicaltrials.gov/ct2/results?term=GetGoal. Date accessed: December 2012.
3. Zealand Pharma pays 13% to Alkermes (former Elan) and 0.5% to SIP® technology inventor on all income from lixisenatide.

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About lixisenatide
Lixisenatide is a glucagon-like peptide-1 receptor agonist (GLP-1 RA) for the treatment of patients with Type 2 diabetes mellitus. GLP-1 is a naturally-occurring peptide hormone that is released within minutes after eating a meal. It is known to stimulate glucose-dependent insulin secretion by pancreatic beta cells and suppress glucagon secretion from pancreatic alpha cells.

Lixisenatide is invented by Zealand Pharma and global rights to the product are licensed to Sanofi. Lixisenatide is the proprietary name approved by the European Medicines Agency (EMA) for the GLP-1 RA lixisenatide.

About GetGoal

The 11 GetGoal clinical trials supporting the lixisenatide NDA filing studied the benefits and risks related to using lixisenatide as monotherapy, in combination with oral anti-diabetic medicines, in combination with basal insulin and versus twice-daily exenatide.

About Zealand Pharma

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand Pharma specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company's focus lies in the field of diabetes/metabolic diseases, and its lead drug invention is lixisenatide, a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide is approved in Europe (February 2013), and under regulatory review in a large number of other countries globally. In February 2013, the FDA accepted for review the NDA submitted for lixisenatide in the US.

Zealand Pharma has a partnering strategy for the development and commercialization of its products and in addition to the collaboration with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury. Zealand Pharma focuses its activities in disease areas where existing treatments fail to adequately serve patient needs and where the market potential for improved treatments through the use of peptide drugs is high. For further information: www.zealandpharma.com

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services and devices, including innovative blood glucose monitoring systems. Sanofi markets both injectable and oral medications for people with Type 1 or Type 2 diabetes.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).